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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,201	05/15/2007	Jean-Pierre Sachetto	SACH3001/ESS	8441
23364 7590 06/10/2009 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314-1176				
EXAMINER				
HUGHES, ALICIA R				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
06/10/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/587,201

Applicant(s)

SACHETTO ET AL.

Examiner

ALICIA R. HUGHES

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-22 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-10, 13-22, and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims and Examination

Claims 1-10, 13-22, and 35-37 are pending and the subject of this Office Action. Applicant cancelled claims 25 and 30-31 in its response of 18 May 2009.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's arguments filed on 18 May 2009 have been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13-22, and 35-37 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,502,077 [hereinafter referred to as "Breivik et al"] (the reference is being considered in its totality) in view of Borkan et al.

The teachings of Breivik et al Borkan et al from this Office's Actions of 28 January 2008, 09 October 2008 and 18 February 2009, as well as the reasoning association therewith, are incorporated herein by reference in their entirety.

Applicants argue that the combination of Breivik and Borkan fails to disclose or suggest the claimed soft gelatin capsule containing Type A gelatin and that neither publication suggests a soft gelatin capsule comprising Type A gelatin that contains a pharmaceutical formulation comprising at least one omega-3-polyunsaturated fatty acid in free acid form. Applicant further surmises that there is no reference teaching a soft gelatin capsule comprising Type A gelatin that exhibits a longer shelf life as compared to a soft gelatin capsule comprising Type B gelatin.

While Applicants have argued that the reference speculates that the EPA and the DHA formulation could be in the form of the free acid. The Examiner takes issue with this point and does note that Breivik is an issued U.S. patent. Therefore, the disclosures therein are presumed valid and therefore, Applicants' assertion that the "reference speculates" and arguments emanating therefrom are but allegations lacking factual support.

With regard to Borkan, even with the claim amendments, it teaches the same thing: that gelatin may be of Type A, Type B or a mixture thereof. Simply stated, therefore, Borkan teaches Type A gelatin. The mere statement that Borkan evidences the unexpected nature and nonobviousness of the claimed invention cannot be presupposed by teachings of two gelatin types only or mixtures thereof. Further, when considering new claims the same still reads on the

existing prior art. While the comprising claim language is open and therefore inclusive, it does not foreclose the possibility of a soft gelatin capsule with Type A gelatin exclusively. And further, the limitation in claim 35 that delineates a methodology of how the shelf life determined is a matter of routine practice to those of ordinary skill in the art.

The Examiner acknowledges the Patent Office's burden to consider objective indicia of nonobviousness when it is present and pursuant to Applicants' request, a more close review of Table 1 on page 10 was undertaken to ascertain whether indeed there were unexpected results. As noted prior in the Office Action and then in the interview, review of the same did not reveal conclusive data to support the Applicants' claim of unexpected results, most especially in analyzing data with storage temperatures at 25 degrees and 30 degrees.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to conclude that the making and administration of a soft gelatin capsule containing EPA and DHA would be effective in the treatment of hypertriglyceridemia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614